
OFFICE OF CLINICAL PHARMACOLOGY

Office of Clinical Pharmacology Briefing Criteria and Attendance Policies

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PURPOSE

- This MAPP establishes a process to determine when briefings in the Office of Clinical Pharmacology (OCP) should be held, who should attend, and what procedures should be followed.
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BACKGROUND

An OCP briefing is an interactive meeting in which the OCP reviewers of a new drug application (NDA) present and discuss with OCP staff and other invited or interested FDA staff important issues related to the NDA review. The primary objective for an OCP briefing is to obtain input from the senior leadership team on issues identified in the NDA review. Other potential benefits of an OCP briefing include:

- Ensuring high scientific quality of OCP reviews
 - Promoting consensus decisions and teamwork
 - Lending consistency in policy to reviews across OCP divisions
 - Identifying scientific needs for new OCP policy development
 - Providing valuable information to OCP staff, medical officers, and other review division staff who are in attendance
 - Providing a forum for early management involvement in preparation for FDA advisory committee meetings
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POLICY

- **Criteria for Holding OCP Briefings and for Attendance**

OCP Division Directors can escalate or de-escalate briefing levels based on the significance and presence or absence of issues in the NDA review. The OCP briefing should be scheduled consistent with the overall NDA review plan and timetable as decided upon in the review division team, so that the OCP briefing process does not interfere with meeting PDUFA goals.

- **Required OCP Office Level Briefings**

In general, Office level OCP briefings are **required** for:

1. NDAs that present unique scientific and/or potential new office policy issues (to be identified by the host OCP division)
2. All NDAs whose drugs are to go to advisory committee meetings and have potentially controversial clinical pharmacology and/or biopharmaceutics issues
3. New molecular entities (NMEs) that are first in a pharmaceutical or therapeutic class
4. All NDAs for which OCP intends to recommend non-approval because of clinical pharmacology and/or biopharmaceutic issues
5. Pediatric supplement NDAs that have potentially complicated/controversial clinical pharmacology and/or biopharmaceutics issues

Attendees:

Required to Attend:	Expected to Attend:	Invited to Attend:
1. OCP primary reviewers. PM, PGx, and QT reviewer as needed	1. OCP Office representative (Director/Deputy Director, and/or Special Asst)	1. Review division staff (e.g., director, medical reviewer, other review team members)
2. CP team leader	2. All OCP division directors and/or deputy directors	3. Staff from all OCP divisions
3. PM, PGx, and QT team leaders as needed		3. OTS staff who have requested notification

- **Required OCP Inter-Division Level Briefings**

In general, inter-division level OCP briefings are **required** for:

1. All NDAs for which the pivotal bioequivalence studies fail to meet established criteria to document the bioequivalence of the clinical dosage form and the to-be-marketed dosage form
2. NDAs with immediate release to controlled/extended release or new/novel dosage forms

Attendees:

Required to Attend:	Expected to Attend:	Invited to Attend:
1. OCP primary reviewers. PM, PGx, and QT reviewer as needed	1. All OCP Division Directors and/or Deputy Directors	1. Review division staff (e.g., director, medical reviewer, review team members)
2. CP team leader		2. OCP Office representative (Director/Deputy Director, and/or Special Asst)
3. PM, PGx, and QT team leaders as needed		3. Staff from all OCP divisions
		4. OTS staff who have requested notification

- **Optional OCP Inter-Division Briefings**

(Note: The need for this type of OCP briefing is to be determined by the OCP division director responsible for the NDA review. The briefing should be held only if there is an obvious need to discuss important issues found during the review.)

Optional inter-division level OCP briefings **may be** held for:

1. NDAs whose drugs are to go to advisory committee meetings but have no controversial clinical pharmacology and/or biopharmaceutics issues
2. NMEs that are not first in a pharmaceutical or therapeutic class
3. NDAs with new routes of administration
4. Pediatric Supplemental NDAs without potentially complicated and/or controversial clinical pharmacology and/or biopharmaceutics issues

Attendees:

Required to Attend:	Expected to Attend:	Invited to Attend:
1. OCP primary reviewers. PM, PGx, and QT reviewer as needed	1. Host division directors and/or deputy directors	1. Review division staff (e.g., director, medical reviewer, review team members)
2. CP team leader		2. Other division directors and/or deputy directors
3. PM, PGx, and QT team leaders as needed		3. Staff from all OCP divisions
		4. OCP Office representative (Director/Deputy Director, and/or Special Asst)
		5. OTS staff who have requested notification

- **Optional OCP Intra-Division Level Briefings**

(Note: The need for this type of OCP briefing is to be determined by the OCP division director responsible for the NDA review. The briefing should be held only if there is an obvious need to discuss important issues found during the review.)

Optional intra-division level OCP briefings may be held for NDAs or supplements related to the following:

1. Most topical drugs/dosage forms

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2. Combination products
3. Formulation changes (except routes of administration)
4. New indications or patient populations
5. Any of the situations identified under optional inter-division level where the inter-division briefings are not held

Attendees:

Required to Attend:	Expected to Attend:	Invited to Attend:
1. OCP primary reviewers. PM, PGx, and QT reviewer as needed	1. Host division director and/or deputy directors	1. Review division staff (e.g., director, medical reviewer, review team members)
2. CP team leader		2. Other division directors and/or deputy directors
3. PM, PGx, and QT team leaders as needed		3. Staff from all OCP divisions
		4. OCP Office representative (Director/Deputy Director, and/or Special Asst)
		5. OTS staff who have requested notification

PROCEDURES

Procedures prior to the OCP Briefing

1. Determining the level and need for an OCP briefing

At the end of the secondary review, the major issues should be identified and discussed between the team leaders and the OCP review team. These issues should be brought forward for discussion with the division director and deputy division director. The purpose of this meeting should be to determine both the need for and the level of the OCP briefing (see POLICY- Criteria for holding OCP briefings).

2. The de-escalation process

If a required OCP Office Level Briefing is to be de-escalated, the office should be informed by the division director and an agreement should be reached. The office should be informed by the division director as necessary of other types of briefings that are to be escalated or de-escalated.

3. Setting up a meeting request

The primary reviewer for an OCP briefing should contact his or her division secretary and provide the following information:

- a. NDA number, drug name, and indication
- b. Preferred dates, times, duration (1 hour or 1.5 hours), and the preferred location for the OCP briefing
- c. Type or level of OCP briefing
- d. List of attendees (refer to the table of attendees under POLICY)

Ideally, the division secretary should schedule the briefing within a day or two of receiving the request from the primary reviewer. In addition to the primary review team and review division staff attendees specified by the reviewer, the secretary should check and schedule other expected attendees as specified under the various tables within the POLICY section of this MAPP.

Any expected attendee who is unable to attend a scheduled OCP briefing is responsible for designating a replacement.

4. Sending the briefing announcement

OCP briefing announcements should be sent a week (5 working days) before the actual briefing date. The electronic draft should be placed on the mutual drive [\\cdsnas\transfer\OCP\briefings](#) and be accessible to everyone on the announcement list.

The briefing announcement should include the following information:

- Date, time, and location of the briefing
- OCP briefing level
- NDA number, drug name, indication
- Primary and secondary reviewers, review division
- Brief background, which includes critical information related to the NDA submission, including whether or not the drug is an NME, first-in-class, and whether or not the proposed indication is new
- Specific scientific and/or policy issue(s) to be discussed at the OCP briefing (if none, so state)
- Overall OCP recommendation
- Phase IV commitments (if any)
- Link to the OCP transfer drive location where the entire review, including the proposed package insert, has been posted

(Note: The briefing announcement should not include the summary of CP findings.)

5. Dry run with division management

At least 2-3 working days before the briefing, a dry run should be held for all required office-level briefings (other levels of briefings, as needed). The required attendees at this dry run should be the Division Director/Deputy Director, and the OCP primary review team. The purpose of this dry run is to review and finalize the briefing slides. The finalized slides should be sent to division management before the briefing.

Procedures at the time of the OCP briefing

1. An OCP briefing should last approximately 1 hour for small NDA reviews that have no complicated scientific and/or policy issues. Longer meetings (i.e., 1.5 hours). should be scheduled for large and/or complicated NDA reviews. The presenter's team leader will serve as facilitator and note recorder.
2. At a minimum, the essential attendees are expected to read the Question Based Review (QBR) portion of the review. Therefore, the briefing should not include detailed descriptive information about the drug and all the studies reviewed. Rather, after the brief introduction the reviewer should focus on the important issues for which the review team is seeking input. The following topics should be addressed at the OCP briefings:
 - **Brief** introduction to the NDA (such as drug, dosage form, route of administration, proposed indications and populations, mechanisms of actions, proposed dosage regimens)
 - Bullet list of key issues to be discussed during the briefing
 - Essential pharmacokinetics characteristics pertaining to the issues
 - Pertinent dose selection information
 - Results of the registration trials and the review division's perspective, as needed
 - Discussion of key issues identified by the review team, followed by OCP's recommendations for these issues, including labeling recommendations, if any
 - Proposed phase IV recommendations (if any) and a discussion related to these
 - Before the meeting adjourns, an overall summary of the discussion by the designated member of the review team

For NDA Reviews Without an OCP Briefing

For all NDA reviews that are covered under the category of optional inter-division and intra-division level OCP briefings, where an OCP briefing is **NOT to be held**, each completed NDA review (i.e., review's synopsis/summary section without appendices) should still be put in the [\\cdsnas\transfer\OCP\briefings](#) directory and an e-mail message sent to OCP staff with an appropriate subject line (e.g., no OCP briefing NDA #) that communicates that a briefing will not be held for the NDA. The e-mail should include the NDA and drug name and the name and location of the NDA review file in the [\\cdsnas\transfer\OCP\briefings](#) directory.

EFFECTIVE DATE

This MAPP is effective upon date of publication.